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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Intravascular Diagnostic and Imaging Medical Devices

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Scientific Information Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of intravascular diagnostic and imaging medical devices, including: Fractional Flow Reserve (FFR), Coronary Flow Reserve (CFR), Intravascular Ultrasound (IVUS), Intravascular Ultrasound (VH-IVUS) with Virtual Histology, Optical Coherent Tomography (OCT), Near-Infrared Spectroscopy (NIR), Angioscopy, Intravascular Magnetic Resonance Imaging (MRI), Elastrography, and Thermography. Scientific information is being solicited to inform our Comparative Effectiveness Review of Intravascular Diagnostic Procedures and Imaging Techniques versus Angiography Alone, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173.

DATES: Submission Deadline on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:
Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/. Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

E-mail submissions: ehcsrc@ohsu.edu (please do not send zipped files - they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239-3098.

FOR FURTHER INFORMATION CONTACT:
Robin Paynter, Research Librarian, Telephone: 503-494-0147 or Email: ehcsrc@ohsu.edu.

SUPPLEMENTARY INFORMATION:
In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for intravascular diagnostic procedures and imaging techniques versus angiography alone.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the Federal Register and direct postal and/or online solicitations. We are looking for studies that report on intravascular diagnostic and imaging medical devices, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: http://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=766#3456

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).

- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.

- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.

- Registered ClinicalTrials.gov studies. Please provide a list including the ClinicalTrials.gov identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting and will not consider marketing material, health economics information, or information on other indications. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter. In addition to your scientific information please submit an index document outlining the relevant information in each file along with a statement regarding whether or not the submission comprises all of the complete information available.

Please Note: The contents of all submissions, regardless of format, will be available to the public upon request unless prohibited by law.

The draft of this review will be posted on AHRQ's EHC program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.

Key Questions

- Key Question 1: For patients undergoing diagnostic coronary angiography to evaluate the presence/extent of Coronary Artery Disease (CAD) in order to decide on the necessity for coronary intervention, what is the impact of using an IVDx technique—when compared to angiography alone—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- Key Question 2: For patients undergoing Percutaneous Coronary Intervention (PCI), what is the impact of using an Intravascular Diagnostic Device (IVDx) technique to guide the PCI procedure (either immediately prior to or during the procedure)—when compared to angiography-guided PCI—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- Key Question 3: For patients having just undergone a PCI, what is the impact of using an IVDx technique to evaluate the success of PCI immediately after the procedure—when compared to angiography alone—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- Key Question 4: How do different IVDx techniques compare to each other in their effects on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- During diagnostic coronary angiography for the evaluation of the presence/extent of CAD and the potential necessity of coronary intervention?

- During PCI to guide the procedure?

- Immediately after PCI to evaluate the success of PCI?

- Key Question 5: What factors (e.g., patient/physician characteristics, availability of prior noninvasive testing, type of PCI performed) influence the effect of IVDx techniques—when compared to angiography (or among different IVDx techniques)—on the diagnostic thinking and therapeutic decision making, short-term outcomes, and long-term outcomes?

- During diagnostic coronary angiography for the evaluation of the presence/extent of CAD and the potential need for coronary intervention?

- During PCI to guide the procedure?

- Immediately after PCI to evaluate the success of PCI?

Dated: NOV 23 2011

Carolyn M. Clancy, M.D.
AHRQ, Director

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